



IN THE UNITED STATES PATENT & TRADEMARK OFFICE

In re Application of

Maximilian Angel et al.

Serial No.09/ 767,821

Filed: January 24, 2001

For: Process for preparing water-soluble or water-dispersible polyether-containing polymers and the use therof as coating agents, binders and/or film-forming excipients in pharmaceutical dosage forms or packaging materials or as additives in cosmetic, dermatological or hygienic preparations

D E C L A R A T I O N

I, Maximilian Angel, Dr. rer. nat., a citizen of Germany and a resident of Bayernstr. 12, 67105 Schifferstadt, Germany, hereby declare and say as follows:

I am a fully trained chemist, having studied chemistry at the Universities of Erlangen and Bayreuth in the period of from 1975 to 1982.

I was awarded my PhD in Physical Chemistry at Bayreuth University, where in the period of from 1982 to 1985 I worked on colloidal systems.

I joined BASF Aktiengesellschaft, located in 67056 Ludwigshafen, Germany, in 1986, and since have been engaged in research and development in the field of polymers .

I am a co-inventor to Application Serial No.09/767,821;

I have carefully studied the Response to Applicant's arguments dated November 23, 2004, the rejection of the claims under 35 U.S.C. § 103

(a) based on the teaching of GB 922,459 in view of the disclosure of Wu et al. (US 5,338,814) which documents I have studied as well.

This is a Supplementary Declaration to my Declaration dated September 30, 2004.

Now, hereby, I want to state the following:

In the Declaration dated September 30, 2004 I stated that no inert diluent is used in GB 922,459. This certainly applies to Example 1 of GB 922,459. Unintentionally, the reference to this Example 1 was not made.

In Examples 4 and 5 a certain amount of methanol added to the polymerization mixture is specified. In Example 6, which refers back to the method of Example 4 no specific amount is mentioned. Methanol can be looked at as an inert diluent. However, the amount of methanol in the polymerization mixture used according to Examples 4 and 5 is so far below the typical amount of inert diluent the skilled person would expect in a normal solution polymerization: Ex. 4: 19.87 wt.-% MeOH; Ex. 5: 6.4 wt.-% MeOH.

By contrast, according to Wu the amount of water in the reaction mixture is from 45-70 wt.-% of water (see claim 2) and approximately 55% according to the examples (see table, col.4).

Insofar the person of ordinary skill in the art will not consider this process of GB '459 as a solution polymerization process. It lies in the very nature of a solution process that a relatively high amount of inert diluent is used in order to allow for a ready control of heat of polymerization. Therefore Wu, who teaches a classical solution polymerization, teaches the use of amounts up to 70% solvent (water).

Notwithstanding this, I want to state again that the skilled person will not look at the process of GB' 459 as a process that can be used

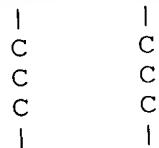
in a safe and efficient manner on a commercial scale for the reasons set out in my previous declaration.

In the Response to Applicant's Arguments the Examiner has pointed out that from Wu's reference a person of ordinary skill in the art would be motivated to use PEG-300 in free radical polymerization because of the advantage of controlling the viscosity build up during polymerization.

However, this motivation does not occur to the person of ordinary skill in the art trying to find an improved and safe method for producing the graft polymers according to the claimed invention, because first of all the solution polymerization process and the product taught by Wu are different from a graft polymerization process and the resulting graft polymer and secondly, the problem of viscosity build-up is not at all an issue in connection with the claimed invention.

The process of GB'459 differs from the process taught by Wu in that GB'459 leads to graft co-polymers of the type

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whereas the process according to Wu leads to a linear homopolymer of the type ---AAAAAAA---

Thus, it should be clear that not only the processes are different, but also the structure of the respective polymers. This is why a person of ordinary skill in the art will consider the teachings of GB'459 and Wu as being so materially different that there is no motivation to combine the two.

For further clarification the following table lists the differences between the teachings of GB'459 and Wu:

	Wu	GB' 459
Type of polymer	homopolymer	Co-polymer
Structure of polymer	linear	Branched (comb-like)
Type of monomer	N-vinyl pyrrolidone; water soluble	Non-water soluble vinyl esters, e.g. vinyl acetate
Type of polymerization process	Solution polymerization in water; 45 to 70 % of aqueous solvent)	Graft polymerization; no or small amounts of organic solvent
Molecular weight distribution	narrow	Not specified, but typically broad due to graft polymerization mechanism

Considering that both references relate to different processes, products with a different structure and the fact that Wu's teaching relates to a very specific problem which cannot necessarily be generalized, the person of ordinary skill in the art will not feel motivated to combine the two teachings.

In addition, I want to point out the following:

The process taught by Wu relates to a polymerization where the monomer N-vinylpyrrolidone (NVP) is polymerized to give **linear** PVP **homopolymers** of a very high molecular weight (K90). As taught by Wu, the solution polymerization of NVP under these conditions will lead to growing linear chains the growth of which must be controlled in order to achieve a narrow molecular weight distribution and to avoid viscosity build-up. This is achieved by using the low molecular polyethylene glycol as a chain transfer agent that interferes with chain growth. Therefore, the skilled person will consider the teaching of Wu solely as being connected to the process of making

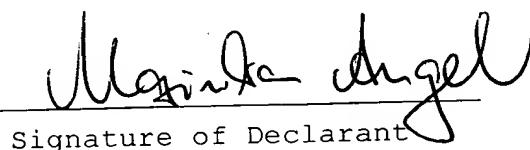
PVP K90, i.e. a high molecular weight linear homopolymer, by aqueous solution polymerization.

More so, as I have stated before, a skilled person might even assume that a substance that functions as a chain-transfer agent might influence the graft polymerization in the sense that it might interfere with the graft polymerization of the vinyl acetate units onto the high molecular polyethylene glycol backbone.

Thus, in my opinion it was not obvious to a skilled person to use a low-molecular polyethylene glycol, which according to Wu serves as a chain-transfer agent, as a solvent for the radical former in the process of GB '459 in order to solve the problem described above.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information or belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so are made punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signed at 67056 Ludwigshafen, Germany, this 7th day of February 2005.



A handwritten signature in black ink, appearing to read "Marinka Angel". The signature is written in a cursive style with a horizontal line underneath it.

Signature of Declarant